

# TheraLife Inc.

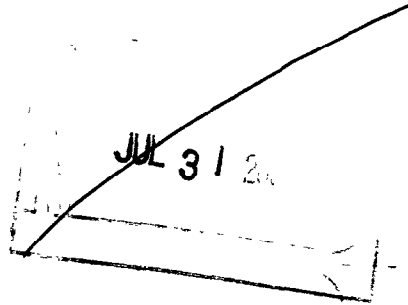
Better Life Through Natural Therapy

960 N. San Antonio Road, Suite 260, Los Altos, CA 94022  
Tel: (650) 994-6080, fax: (650) 949-6083  
[www.TheraLife.com](http://www.TheraLife.com)

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June 15, 2005

Office of Special Nutritional (HFS-450)  
Center for Food Safety and Applied Nutrition  
Food and Drug Administration  
200 C Street SW  
Washington, DC 20204



JUL 13 2005

## Notification Letter for Statement on Dietary Supplement

Dear FDA Officers:

This notification is being filed on behalf of TheraLife, Inc., which is the manufacturer of the product, which bears the statements identified in the notification. This notification is being made pursuant to Code of Federal Regulations, Volume 21, Part 101.93 to notify you that we have included a statement on the label or in the labeling of one of our products. The following are the information required in this notification letter:

### 1. Statement of Purpose:

This is a letter to provide notification of a statement of nutritional support, including the exact wording that appears on the label and labeling for a dietary supplement.

### 2. Vendor Information:

Name, address, telephone and fax numbers of the manufacturer and distributor for mailing and other communication purposes are as follows:

TheraLife, Inc.  
960 N. San Antonio Road, Suite 260  
Los Altos, CA 94022  
Tel: (650) 949-6080  
Fax: (650) 949-6083

The above address is also used for consumer inquiries.

2005-4359  
AFMS

975 0162 LET 16408

### 3. Product Identification:

The trade name of the product:

Regena-Vue™

The common and usual name of the product:

None

A label copy showing all information displayed and provided to consumers is attached.

### 4. The text of the Structure/Function Statement:

Macular Regeneration

### 5. Ingredient Statement:

This product is a Vitamin/Mineral/Herb product with a proprietary blend of herbs. The following is a complete list of dietary ingredients:

Vitamin E  
Vitamin C  
Vitamin B2  
Beta Carotene  
L-Carnitine  
Zinc  
Selenium  
Copper  
Proprietary Herbal Blend

Common Name	Chinese Name	Latin Name	Part of Plant
Fructus Lycii	Gouqizi	Lycium barbarum L	Seed
Flos Chrysanthemi	Juhua	Chrysanthemum morifolium	Flower
Semen Cassiae	Juminzi	Cassia obtusifolia L	Seed
Bilberry	None	Vaccinium myrtillus	Fruit
Radix Glycyrrhizae	Gancao	Glycyrrhiza uralensis Fischer	Root

## 6. Intended Use:

This product is intended to be used by adult over the age of 18.

Suggested use: Adults take 8 capsules with water a day.

Warning: Store at room temperature and avoid excessive heat. Use for adults only and not for pregnant or nursing women. Bottle cap should be foil sealed.

## 7. Statement of Affirmation:

We, as a manufacturer and distributor of the above mentioned product, affirm that we have substantiation that the structure/function statement ( as shown in No. 4 above ) made under 403(6)(r) of the Federal Food, Drug and Cosmetic Act is truthful, not misleading, and scientifically valid and that the product does not present a significant or unreasonable risk of illness or injury under the conditions of use recommended or suggested in the label or labeling.

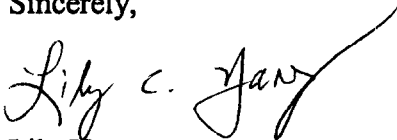
## 8. Disclaimer:

The disclaimer reads:

The statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat cure, or prevent any disease.

Should there be any question or comment, please contact the Vendor through the information in No. 2 above.

Sincerely,



Lily Yang  
President and Chief Executive Officer